

MINERAL OIL, PRAMOXINE HYDROCHLORIDE AND ZINC OXIDE - mineral oil, pramoxine hydrochloride and zinc oxide cream

CVS Pharmacy

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

drug facts

Active ingredients	Purpose
Mineral Oil 46.8%.....	Protectant
Pramoxine HCL 1%.....	Pain Reliever
Zinc Oxide 12.5%.....	Protectant

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Uses

- temporarily relieves these local symptoms associated with hemorrhoids and other anorectal disorders:
- pain - soreness - burning - itching
- temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Other information - store at 20 degrees - 25 degrees C (68 degrees - 77 degrees F)

Warnings

For external use only.

When using this product

- do not use more than directed unless told to do so by a doctor
- do not put into rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- allergic reaction occurs
- rectal bleeding occurs
- redness, irritation, swelling pain or other symptoms begin or increase

- condition worsens, or does not improve within 7 days

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

Adults: apply externally to the affected area up to 5 times daily

- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or soft cloth before applying
- to use dispensing cap:
 - attach it to tube, lubricate well, then gently insert partway into anus
 - squeeze tube to deliver medication
 - thoroughly cleanse dispensing cap after use

Children under 12 years of age: ask a doctor

Inactive Ingredients

benzyl benzonate, dicalcium phosphate, glyceryl oleate, glyceryl stearate, kaolin, peruvian balsam, polyethylene, theobroma cacao (cocoa) seed butter



MINERAL OIL, PRAMOXINE HYDROCHLORIDE AND ZINC OXIDE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-399
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	466 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	125 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
COCOA BUTTER (UNII: 512OYT1CRR)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERYL MONOOLEATE (UNII: 4PC054V79P)	
KAOLIN (UNII: 24H4NWX5CO)	
BALSAM PERU (UNII: 8P5F881OCY)	
BENZYL BENZOATE (UNII: N863NB338G)	
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-399-03	1 in 1 CARTON		
1		28 g in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/16/2010	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 7/2010

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